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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,003 11/30/2001 Craig A. Rosen PA003P1 7261

22195 7590 09/29/2003

HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE, MD 20850

[REDACTED]  
EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/997,003</b>	Applicant(s) <b>Rosen</b>
	Examiner <b>Arun Chakrabarti</b>	Art Unit <b>1634</b>
		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on Nov 30, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 1-24 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-24 are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Dreftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: *Detailed Action*

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***DETAILED ACTION***

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10 and 22, drawn to nucleic acids, classified in class 536, subclass 22.1.
  - II. Claims 11-14, drawn to polypeptides, classified in class 530, subclass 350.
  - III. Claims 15-16, drawn to method of making polypeptides, classified in class 435, subclass 69.1.
  - IV. Claims 17 and 18, drawn to prevention of disease, classified in class 514, subclass 44.
  - V. Claims 19, 20, and 24 drawn to diagnosis of disease, classified in class 435, subclass 6.
  - VI. Claims 21 and 23, drawn to antigen-antibody reaction, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

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806.05(h)). In the instant case, the diagnosis of disease of Group V can be practiced with nucleic acids of Group I or with polypeptides and antibodies.

3. Inventions of Groups I and II-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of nucleic acids are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects than polypeptides, method of making polypeptides and prevention of disease of Groups II-IV and VI.

4. Inventions of Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antigen-antibody reaction of Group VI can be practiced with polypeptides and antibodies of Group II or with nucleic acids of Group I

5. Inventions of Groups II and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups II and III-V are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects .

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6. Inventions of Groups III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups III and IV-VI are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects .

7. Inventions of Groups IV and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups IV and V-VI are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

8. Inventions of Groups V and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because diagnosis of disease can be practiced with nucleic acid hybridization.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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10. A telephone call was made to Michele Wales on September 22, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Conclusion*

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau, whose telephone number is (703) 605-1237.

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**Arun Chakrabarti,**

**Patent Examiner**

**September 22, 2003**

*Gary BenZion*  
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SUPERVISORY PATENT EXAMINER  
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